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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
04/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/554,409	GRONLUND ET AL.	
	Examiner	Art Unit	
	NORA ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/09/2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,28,33-40 and 42-47* is/are pending in the application.

4a) Of the above claim(s) *34-36,39 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,28,33,37,38 and 42-47* is/are rejected.

7)☒ Claim(s) *22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 12/09/2010 is acknowledged.

2. Claims 22, 28, 33-40, 42-47 are pending.

3. Claims 34-36 and 39-40 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/16/2010.

4. Claims 22, 28, 33, 37-38 and 42-47 are currently under consideration as they read on a recombinant Fel d 1 fusion product comprising a Fel d 1 chain 1 and a Fel d 1 chain 2 linked by carbon-nitrogen bond wherein the N- terminal amino acid of chain 1 is lined to the C-terminal amino acid of claim 2, pharmaceutical compositions and kits thereof.

Claim Objections

5. Claim 22 objected to because of the following informalities: Claim 22 is missing the word "and" instead of a comma between the phrases "Fel d 1 chain 1" and "Fe ld 1 chain 2." Appropriate correction is required.

6. The following rejections are necessitated by the amendment filed on 12/09/2010.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 22, 28, 33, 37-38 and 42-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 22 recites variants to SEQ ID NO:1 and SEQ ID NO:2. However, it is unclear if the variants encompass all of the amino acid changes or a subset of the amino acid changes listed within a single variant. If Applicant intends for all of the amino acid changes to be present, then it is unclear how two amino acid changes to the same amino acid can be detected as recited in the variants to SEQ ID NO:1 comprising both Arg and Asn at position 29. Clarification in the claims regarding the mutation strategy employed in the variants is required.

B. Claim 22 recites variants to SEQ ID NOs 1 and 2 comprising specified mutations. However, the claimed variants of SEQ ID NOs 1 and 2 encompass any variant that has the specified mutations including polypeptides of no relation to SEQ ID NOs 1 and 2 so long as they are encompassed by the term "variant" as defined by the specification.

C. Claim 45, which is dependent upon claims 44 and 42 recites that the fusion protein comprises SEQ ID NO:4. However, SEQ ID NO:4 does not comprise the limitations of claims 42 and 44, namely amino acids added onto the N- and/or C-terminus of the fusion protein. It is more appropriate and clear to have claims 42 and 44 depend upon claim 45 instead of the other

way around.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 22, 28, 33, 37-38 and 42-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: the polypeptides of SEQ ID NO: 1, 2, 3 and fusions thereof (including SEQ ID NO:4) and compositions and kits thereof, does not reasonably provide enablement for: the polypeptide variants recited in claim 22.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The term 'comprising ' is open language. As written, the claims encompasses an enormous number of undisclosed polypeptide variants that may include sequence that is unrelated to the polypeptides of SEQ ID NO:1 and 2.

Claim 22 recites mutations to SEQ ID NOs 1 and 2. However, as recited, the claims read on polypeptide variants having any number of mutations in addition to the ones listed in claim 22. Absent a limiting definition in the specification, the recited polypeptide variant reads on all polypeptides which comprise those specific mutations. It is suggested that Applicant amend the claims to recite that the variants consist of SEQ ID NOs 1 or 2 with the recited mutations.

There is insufficient guidance in the specification as filed as to how the skilled artisan would make the various variants recited in the instant claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences of a polypeptide variant that is encompassed by the instant claim recitation. There is insufficient guidance to direct a person of skill in the art to select particular sequences or sequence lengths as essential for the claimed functions. Without detailed direction as to which sequences are essential to the function of the encoded polypeptide, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of protein and peptide sequences encompassed by the instant claims would exhibit the claimed functional characteristics and which can be used in a pharmaceutical composition.

Also at issue is whether or not the genus of claimed compositions would function as pharmaceutical compositions. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical compositions are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the changes which can be made in the

instantly recited polypeptide that maintains the functional properties of the polypeptides of SEQ ID NOs 1 and 2 is unpredictable, as is the identity of which subsequences would encode a functional polypeptide; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

11. Claims 22, 28, 33, 37-38 and 42-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of polypeptides of SEQ ID NO:1, 2 or 3 and fusions thereof (including SEQ ID NO:4) and compositions and kits thereof

Applicant is not in possession of **polypeptide variants of SEQ ID NOs 1 and 2 as recited in claim 22**.

The "comprising" language of claim 22 combined with the term variant reads on a genus of variants that have not been adequately described in the specification. The recited polypeptide variants may comprise any number of additional mutations to SEQ ID NOs 1 and 2, so long as they comprise the recited mutations. Essentially, the recited mutations are the only necessary structure for the recited variants because they may encompass any number of further mutations,

deletions and additions. The specification has not adequately described a genus of such variants that can be used for the disclose functions and to be able to be used pharmaceutically.

Applicant has disclosed only polypeptides of SEQ ID NOs NO:1, 2 and 3 fusions thereof and compositions and kits thereof; therefore, the skilled artisan cannot envision all the contemplated variant polypeptide possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 22 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,048,962 (PTO-892; Reference A).

U.S. Patent 6,048,962 teaches the Fel d 1 allergen comprising chain 1 of reference SEQ ID NO:2 (comprising instant SEQ ID NO:1) and chain 2 of reference SEQ ID NO:6 (comprising

SEQ ID NO:2) covalently bonded and a kit thereof with instructions for use. (In particular, claims 1-19, paragraph 83, whole document).

The reference teachings anticipate the claimed invention.

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 28, 2011

/Nora M Rooney/

Examiner, Art Unit 1644